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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/594,835

09/28/2006

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21538YP

3654

210 7590 08/29/2008  
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EXAMINER

LOEWE, SUN JAE Y

ART UNIT

PAPER NUMBER

1626

MAIL DATE

DELIVERY MODE

08/29/2008

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/594,835	<b>Applicant(s)</b> COBURN ET AL.	
	<b>Examiner</b> SUN JAE Y. LOEWE	<b>Art Unit</b> 1626	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 16 June 2008.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 21, 22 and 24 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 21, 22 and 24 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

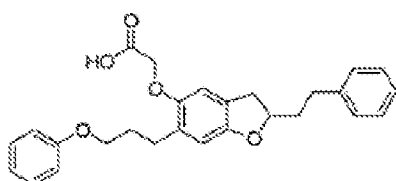
- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                       | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | Paper No(s)/Mail Date. _____                                      |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>9-28-06; 6-16-08</u> .  | 6) <input type="checkbox"/> Other: _____                          |

### DETAILED ACTION

1. Claims 21, 22 and 24 are pending in the instant application.

#### *Election/Restrictions*

2. Applicant's election without traverse of Group III, and species of Example 1 (structure below), in the reply filed on June 16, 2008 is acknowledged.



The restriction requirement between Groups I-III is hereby made FINAL.

3. Pursuant MPEP 1893.03

#### *“(Excerpts)”*

Once the national stage application has been taken up by the examiner, prosecution proceeds in the same manner as for a domestic application with the exceptions that:

(A) the international filing date >(or, if appropriate, the priority date)< is the date to keep in mind when searching the prior art; and

(B) unity of invention proceeds as under 37 CFR 1.475.

.....

¶ 18.20 National Stage Election of Species in 35 U.S.C.

*371 Applications*

This application contains claims directed to more than one species of the generic invention. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.

The species are as follows:

**[1]**

Applicant is required, in reply to this action, to elect a single species to which the claims shall be restricted if no generic claim is finally held to be allowable. The reply must also identify the claims readable on the elected species, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(s). ”

the search and examination detailed in this office action was performed following the guidelines provided by MPEP 803.02

*“(Excerpts)”*

Markush-type claim will be examined fully with respect to the elected species and further to the extent necessary to determine patentability. If the Markush-type claim is not allowable \*\*, the provisional election will be given effect and examination will be limited to the Markush-type claim and claims to the elected species, with claims drawn to species patentably distinct from the elected species held withdrawn from further consideration.

If on examination the elected species is found to be anticipated or rendered obvious by prior art, the Markush-type claim and claims to the elected species shall be rejected, and claims to the non-elected species would be held withdrawn from further consideration.”

The elected compound was not allowable. Furthermore, prior art was found that anticipates a non-elected species encompassed by the generic claims. Therefore, the provisional election of species was given effect and non-elected species were withdrawn from further consideration.

***Information Disclosure Statement***

4. The information disclosure statements (dated September 28, 2006 and June 16, 2008) were filed in compliance with the provisions of 37 CFR 1.97 and 37 CFR 1.98. The statements were considered. Signed copies of form 1449 are enclosed herewith.

***Specification Objections***

5. The specification is objected to for the following reason. The first line of the specification does not identify the correct filing date of the priority document 60/558,855. Appropriate correction is requested.

***Claim Objections***

6. Claims 21, 22 and 24 objected to for containing non-elected subject matter. The non-elected subject matter consists of compounds of Formula I that are not the elected species. Applicant will be entitled to rejoinder of non-elected species upon allowability of the generic claims.

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

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(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

7. Claims 21 and 22 rejected under 35 U.S.C. 102(b) as being anticipated by Belanger et al. (US 5,091,533). The reference teaches a leukotriene biosynthesis inhibitor that is encompassed by the instant claims (compound 38, Table 1 columns 85 & 86; R2=R5=H; R4=R6=chloro; R3=-(CH<sub>2</sub>)<sub>n</sub>=3-phenoxy).

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

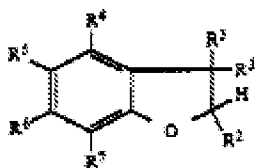
The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
  2. Ascertaining the differences between the prior art and the claims at issue.
  3. Resolving the level of ordinary skill in the pertinent art.
  4. Considering objective evidence present in the application indicating obviousness or nonobviousness.
8. Claims 21, 22 and 24 rejected under 35 U.S.C. 103(a) as being obvious over Belanger et al.

*Determination of the scope and contents of prior art .*

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The reference teaches the following genus of leukotriene biosynthesis inhibitors:



, including preferred embodiments which include the compound of

No.	-R <sup>5</sup>	-R <sup>3</sup> /R <sup>3</sup>	-R <sup>4</sup>	-R <sup>2</sup>	-R <sup>1</sup>	-R <sup>7</sup>
77	CH <sub>2</sub> CH <sub>2</sub> Ph	H/H	H	O(CH <sub>2</sub> ) <sub>4</sub> COOH	X-OPh	H

Variable R5 is generically taught to be hydroxyl or metabolizable to hydroxy.

Ascertaining the differences between prior art and instant claims.

The following modification to the prior art compound No. 77 results in the instant elected species: decrease the alkyl chain length from C4 to C1. Thus, the prior art compound is a homolog of the instant elected species.

Resolving the level of ordinary skill in the pertinent art – Prima Facie Case of Obviousness.

To those skilled in chemical art, one homologue is not an advance over an adjacent member of a homologous series. The reason for this is that one of ordinary skill, knowing the properties of one member of series, would know what properties to expect in adjacent members. In re Henze, 85 USPQ 261 (1950). In re Wood, 199 U.S.P.Q. 137 (C.C.P.A. 1978) and In re Lohr, 137 U.S.P.Q. 548, 549 (C.C.P.A. 1963).

One of ordinary skill would be motivated, from the prior art disclosure – ie. generic teaching for R5 and disclosed species - to make the modification required to arrive at the instant invention with reasonable expectation of success for obtaining an additional compound for the same utility. The motivation would be to make additional leukotriene biosynthesis inhibitors.

Thus, the instant claims are *prima facie* obvious over the teaching of the prior art.

***Conclusion***

9. No claims allowed.

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sun Jae Y. Loewe whose telephone number is (571) 272-9074.

The examiner can normally be reached on M-F 7:30-5:00 Est.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph McKane can be reached on (571)272-0699. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Sun Jae Y. Loewe, Ph.D./  
8-14-2008

/Kamal A Saeed, Ph.D./  
Primary Examiner, Art Unit 1626